

### **REMARKS**

Claims 1-12, 30, 31, 42, and 43 were pending in the application. Claims 6-10, 30, 31, 42 and 43 have been canceled as being directed to non-elected inventions. Claims 1 and 2 have been amended and claim 5 has been cancelled by the amendments presented herein. Support for the amendments to the claims can be found in the specification and claims as originally filed. Accordingly, after the amendments presented herein have been entered, claims 1-4, 11 and 12 will remain pending. No new matter has been added.

### ***Priority***

The Examiner has indicated that the priority claim is acknowledged but that the pending claims do not properly benefit from the earlier filed applications. Applicants respectfully disagree.

The Examiner believes that the provisional application does not provide support for the pending claims and that, at best, it provides support only for methods for diagnosing prostate cancer (see page 3 of the office action).

Applicants strongly disagree with the Examiner and point out that even if the Examiner were correct, the priority date that the instant claims would be entitled to would be the priority date of the PCT application (25 April 2003) and not the date of filing of the instant application (October 26, 2004) as asserted on the bottom of page 3 of the office action.

While in no way acquiescing to the validity of the Examiner's argument, and solely in the interest of expediting prosecution, Applicants have amended the claims to be directed to methods of diagnosing prostate cancer and are therefore entitled to the earliest claimed priority date (April 26, 2002) as indicated by the Examiner.

Accordingly, Applicants respectfully request that the Examiner acknowledge that the claimed subject matter is entitled to the benefit to the filing date of the provisional application.

### ***Specification***

The Examiner has objected to the specification because of improperly demarcated trademarks. Applicants have amended the specification to properly identify proprietary names. Accordingly, Applicants respectfully request withdrawal of this rejection.

### ***Claim Objections***

The Examiner has objected to the claims as being directed to non elected subject matter. Applicants have amended the pending claims thereby rendering this rejection moot.

### ***Rejection of Claims 1-5, 11 and 12 Under 35 USC 112, Second Paragraph***

The Examiner has rejected claims 1-5, 11, and 12 under 35 USC 112, second paragraph as being indefinite over the use of the terms "prostate cancer status". While in no way acquiescing to the validity of the Examiner's rejection, and solely in the interest of expediting prosecution, Applicants have amended the claims to be directed to methods of determining if a subject has prostate cancer.

Accordingly, Applicants believe that the foregoing rejection has been rendered moot and respectfully requests withdrawal of the rejection.

### ***Rejection of Claim 4 Under 35 USC 112, Second Paragraph***

The Examiner has rejected claim 4 under 35 USC 112, second paragraph as being indefinite because, allegedly, the metes and bounds of the claimed subject matter are not clear. Applicants respectfully traverse.

The Examiner alleges that the claim is unclear if the practitioner selects to manage treatment by taking no further action. Applicants disagree. The claims, as amended, are directed to methods for diagnosing prostate cancer. A clinician of ordinary skill in the art would find the claims to be clear and definite as pending. It

would be clear to a clinician that if a subject is determined not to have cancer that the appropriate way to manage the subject is by "taking no further action".

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

***Rejection of Claims 1-5, 11 and 12 Under 35 USC 112, First Paragraph***

The Examiner has rejected claims 1-5, 11 and 12 under 35 USC 112, first paragraph as not being enabled. While in no way acquiescing to the validity of the Examiner's rejection, and solely in the interest of expediting prosecution, Applicants have amended the claims to be directed to methods for diagnosing prostate cancer by measuring the amount of Marker I in a sample, wherein a decrease in the amount of the marker as compared to a control is indicative that the subject has prostate cancer.

The Examiner indicates in the Office Action that the specification teaches an association between an abnormal level of Biomarker I in a sample and the presence of prostate cancer. Accordingly, the claims as amended are enabled by the specification as filed.

Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejection.

***Rejection of Claims 1-5, 11 and 12 Under 35 USC 102(a)***

The Examiner has rejected claims 1-5, 11, and 12 under 35 USC 102(a) as being anticipated by Tsuneki et al. Applicants respectfully traverse this rejection.

As indicated above, Applicants are entitled to the benefit of the PCT and the US provisional application. Accordingly, the priority date to which the instant application is entitled is April 26, 2002. Tsuneki et al. was published in 2004, clearly after the priority date of the instant invention. Accordingly, Tsuneki et al is not available as art against the pending claims.

Moreover, even if *arguendo* Tsuneki et al. was available as art, against the pending claims are patentable over this reference. Tsuneki et al. does not teach or suggest a biomarker that is at least 7808 kDa and correlated with the presence or absence of prostate cancer.

***Rejection of Claims 1-5, 11 and 12 Under 35 USC 102(a)***

The Examiner has rejected claims 1-5, 11, and 12 under 35 USC 102(a) as being anticipated by Gretzer et al. Applicants respectfully traverse this rejection.

As indicated above, Applicants are entitled to the benefit of the PCT and the US provisional application. Accordingly, the priority date to which the instant application is entitled is April 26, 2002. Gretzer et al. was published in 2004, clearly after the priority date of the instant invention. Accordingly, Gretzer et al. is not available as art against the pending claims.

Moreover, even if *arguendo* Gretzer et al. was available as art, the pending claims are patentable over this reference. Gretzer et al. does not teach or suggest a biomarker that is at least 7.808 kDa and correlated with the presence or absence of prostate cancer. The Examiner indicates that Gretzer teaches a biomarker that is 9 kDa and that "9 kDa is about 7.808 kDa". Applicants respectfully disagree.

As the Examiner indicates in the office action, Applicants define the term "about" as used in the application. "About", when referring to the mass of the biomarkers, is defined to include the variances in mass accuracy and in the operation of the instrument. The definition at paragraph [0017] defines the variances to be within 0.15% of the actual mass value. Accordingly, based on the teachings in the specification, biomarkers that are "about" 7.808 kDa will have molecular weights that range from 7.796 kDa to 7.820 kDa. Clearly, 9 kDa is not within the range that is "about" 7.808 kDa.

***Rejection of Claims 1-5, 11 and 12 Under 35 USC 102(b)***

The Examiner has rejected claims 1-5, 11, and 12 under 35 USC 102(b) as being anticipated by Cazares et al. Applicants respectfully traverse this rejection.

The Examiner alleges that Cazares et al. teach biomarkers that are about 7.808 kDa. Specifically, the Examiner indicates that Cazares et al. teach biomarkers that are about 6.913, 7.368, and 8.238 kDa. For the reasons indicated above, these biomarkers are not "about" 7.808 kDa.

As indicated above, Applicants define the term "about" as used in the application. "About", when referring to the mass of the biomarkers, is defined to include the variances in mass accuracy and in the operation of the instrument. The definition at paragraph [0017] defines the variances to be within 0.15% of the actual mass value. Accordingly, based on the teachings in the specification, biomarkers that are "about" 7.808 kDa will have molecular weights that range from 7.796 kDa to 7.820 kDa. Clearly, biomarkers that have masses of 6.913, 7.368, and 8.238 kDa are not within the range that is "about" 7.808 kDa.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

**Conclusion**

In view of the above arguments and amendments, Applicants believe the pending application is in condition for allowance. If a phone call with the Applicant's attorney would help to expedite prosecution, the Examiner is urged to contact the undersigned.

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Respectfully submitted,

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